UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN, the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, *ex rel.*, and OSWALD BILOTTA, Plaintiff and Relator, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	No. 11 Civ. 00071 (PGG) **JURY TRIAL DEMANDED**

THIRD AMENDED FALSE CLAIMS ACT COMPLAINT

The facts alleged in this Third Amended *qui tam* Complaint establish that Defendant, Novartis Pharmaceuticals Corporation, committed a massive fraud at the expensive of taxpayers with regard to its sales and marketing of its drugs Lotrel, Valturna, Starlix, Tekturna (including Tekturna HCT), Diovan (including Diovan HCT) and Exforge (including Exforge HCT). For example, through a widespread kickback campaign, Novartis took a mediocre hypertensive drug that was no more effective than existing drugs, including numerous generics, and fraudulently

spun it into Lotrel, a blockbuster brand drug falsely hyped as the superior pharmacological solution.

Incredibly, the Defendant in this case has already been apprehended for the exact same type of misconduct at issue herein. Specifically, in September 2010, the company publicly announced that it agreed to pay approximately $422 Million in criminal and civil fines and penalties to resolve claims that it had paid kickbacks to prescribers of Trileptal, Diovan, Zelnorm, Sandostatin, Tekturna, and Exforge, in addition to claims that the company had promoted some of these drugs for unapproved uses. The first-filed *qui tam* case that led to the 2010 settlement was captioned as *U.S. ex. rel. Austin and Montgomery v. Novartis Pharma. Corp.*, 03-CV-1551 (M.D. Fla.). Notably, following the September announcement, Novartis continued to engage in the same wrongful conduct that was the subject of the settlement, both with respect to certain drugs that were addressed by the settlement and other drugs which were not expressly covered by the settlement.

I. INTRODUCTION

1. On behalf of the United States of America ("United States"), the States of California, Connecticut, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington and Wisconsin (collectively, the "States"), the District of Columbia ("D.C."), and the City of Chicago ("Cities"), and pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729-3733 and the False Claims Acts of the States, D.C., and the Cities, Plaintiff-Relator Oswald Bilotta files this *qui tam* Complaint against Defendant,

NOVARTIS PHARMACEUTICALS CORPORATION (hereinafter referred to as "NOVARTIS," "Defendant," or the "Company").

2. Plaintiff- Relator, Oswald Bilotta ("Plaintiff-Relator"), brings this action on behalf of the United States, the States, D.C., and the Cities against NOVARTIS for treble damages and civil penalties arising from NOVARTIS' conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), and each of the States', D.C., and the Cities' counterparts. The States, D.C., and the Cities, along with the UNITED STATES, are hereafter collectively referred to as the "Government."

3. The complained of violations arise out of requests for payment by Medicare, Medicaid, TRICARE, and possibly other federally-funded government healthcare programs (hereinafter referred to as "Government Healthcare Programs").

4. NOVARTIS is a subsidiary of Novartis AG, a world-wide pharmaceutical company engaged in the development, manufacturing and marketing of pharmaceutical products. It is domiciled in the State of New Jersey, and does business throughout the United States, including in the Southern District of New York. Upon information and belief, its parent corporation, Novartis Corporation, is located at 608 Fifth Avenue, New York, NY 10020, and it has offices at 25 Old Mill Road, Suffern, NY 10901.

5. This case involves unlawful promotional practices by the Cardiovascular Diseases ("CV") Division of NOVARTIS. Simply put, Defendant illegally induced physicians to write prescriptions for Lotrel, Valturna, Starlix, Tekturna (including Tekturna HCT), Diovan (including Diovan HCT) and Exforge (including Exforge HCT) (the "Covered Drugs") through a wide array of kickback and unlawful marketing schemes including, but not limited to:

- hiring and paying physicians as "consultants" or "speakers" as part of a Speakers Bureau to improperly influence other physicians to prescribe the Covered Drugs;

- paying physicians cash and cash equivalents to switch patients from other medications to the Covered Drugs;

6. These practices were widespread, egregious and orchestrated from the highest levels of NOVARTIS.

7. In September 2010, NOVARTIS entered into a settlement agreement with the United States Department of Justice, whereby it agreed to pay more than $422 million to resolve criminal charges and civil liabilities arising out of NOVARTIS' payment of the same type of kickbacks and unlawful marketing practices at issue herein (the "2010 Settlement"). Although the complained of unlawful kickbacks involving many of the Covered Drugs have been taking place since in or about 1999, upon information and belief, NOVARTIS did not disclose its unlawful activities regarding Lotrel, Valturna and Starlix, as detailed herein, to the Federal Government during its settlement discussions which culminated in the 2010 Settlement.

8. As part of the 2010 Settlement, Novartis entered into a Corporate Integrity Agreement ("CIA").

9. Plaintiff-Relator's employment with Defendant commenced on April 15, 1999.

10. Plaintiff-Relator has complied with all procedural requirements of the laws under which this case is brought.

11. Plaintiff-Relator is informed and believes that the pervasive kickbacks and false claims alleged herein began at the latest in 1999 and continue to date, notwithstanding the 2010 Settlement and CIA.

II. FEDERAL JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. This Court has supplemental jurisdiction over the counts relating to the state False Claims Acts pursuant to 28 U.S.C. § 1367.

13. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant can be found in, resides, or transacts business in this District. Additionally, this Court has personal jurisdiction over Defendant because acts prohibited by 31 U.S.C. § 3729 occurred in this District.

14. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

15. Plaintiff-Relator's claims and this Complaint are not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).

16. Plaintiff-Relator is the original source of the information upon which this Complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

17. Plaintiff-Relator brings this action based on his direct knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4), and Plaintiff-Relator is an original source of the facts alleged in this Complaint.

18. At all times relevant hereto, Defendant acted through its agents and employees, and the acts of Defendant's agents and employees were within the scope of their agency and

employment. The policies and practices alleged in this Complaint were, on information and belief, established and/or ratified at the highest corporate levels of Defendant.

III. THE REGULATORY ENVIRONMENT

19. Pursuant to the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE.

20. The Anti-Kickback Act is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

21. Every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

22. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a purpose of the payment is to influence the provider's prescribing habits or to gain favor for its product over the product of any competitor.

23. A violation of the Anti-kickback Act is a violation of the federal False Claims Act (the "FCA"). The FCA, 31 U.S.C. § 3729, provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;

* * *

> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

24. The United States Food, Drug and Cosmetic Act ("FDCA") establishes the framework for regulation of, *inter alia*, the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. When the United States Food and Drug Administration ("FDA") approves a drug, it approves the drug only for the particular use for which it was tested.

25. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from *marketing or promoting* a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It therefore is illegal for a drug manufacturer and its sales representatives to initiate discussions with medical professionals regarding any off-label use of a drug.

26. The dissemination of information or materials by a pharmaceutical manufacturer of any unapproved or off-label use, also known as "misbranding," constitutes unlawful promotional advertising of the drug, violates the FDCA, and can also serve as the basis for an FCA violation.

27. In addition to prohibiting manufacturers from directly marketing and promoting a drug's unapproved use, Congress and the FDA have acted to prevent manufacturers from employing indirect methods to accomplish the same end. For example, the FDA regulates two of the most prevalent indirect promotional strategies: (A) manufacturer dissemination of medical

and scientific publications concerning the off-label uses of their products; and (B) manufacturer support for Continuing Medical Education ("CME") programs and "speaker" programs that focus on off-label uses.

28. With regard to the first practice – disseminating written information – the FDCA allows a manufacturer to disseminate information regarding off-label usage only in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use, and has provided the materials to the FDA for review prior to dissemination. The materials must be submitted in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c);360aaa-1.

A. The FCA and the Medicare Fraud & Abuse/Anti-Kickback Statute

29. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1)(A)&(B). The States, D.C., and the Cities that are parties to this Complaint have enacted False Claims Act statutes that similarly apply to Medicaid fraud and/or fraudulent health care claims submitted for payment by municipal funds.

30. The Medicare Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs and/or municipal programs, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the

referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years.

31. The Medicare Anti-Kickback statute arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs from these difficult-to-detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

32. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback statute to include administrative civil penalties of $50,000 for each violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

33. In accordance with the Medicare Anti-Kickback statute, applicable regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). Thus, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order to recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits

any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

34. Such remunerations are kickbacks when paid to induce or reward physicians' prescriptions. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as physicians may prescribe drug products based on the physician's own financial interests rather than according to the patient's medical needs.

35. The Medicare Anti-Kickback statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects NOVARTIS from liability for the conduct alleged herein.

36. Recently, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, § 6402(g), amended the Medicare Anti-Kickback statute (a/k/a "Social Security Act"), 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the FCA. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h).

37. As detailed herein, NOVARTIS devised a scheme whereby it paid kickbacks to consultants, speakers and physicians in the form of massive amounts of cash and cash equivalents with the specific aim of artificially increasing the usage of the Covered Drugs.

38. Knowingly paying kickbacks to physicians to induce them to prescribe a prescription drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a federal Government health program or causing others to do so, while certifying compliance with the Medicare Anti-Kickback Statute (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

B. Stark Law – The Medicare/Medicaid Self-Referral Statute

39. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. §1395nn, *et seq*., also known as the "Stark Law," prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain "designated health services," including drug prescriptions, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). The Stark Law provides that the manufacturer shall not cause to be presented a Medicare or Medicaid claim for such prescriptions. The Stark Law also prohibits payment of claims for prescriptions rendered in violation of its provisions. 42 U.S.C. § 1395nn(a)(1), (g)(1).

40. Knowingly paying physicians to induce them to prescribe a prescription drug on-label or off-label for individuals seeking reimbursement for the drug from a federal health program or causing others to do so, while certifying compliance with the Stark Law (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and the state False Claims Acts.

41. NOVARTIS' conduct alleged herein repeatedly violated the Stark Law, which in turn resulted in violations of the FCA, because NOVARTIS' unlawful payments and services to

prescribing physicians induced (and still induces) those physicians to prescribe certain drugs, including but not limited to, Lotrel, Valturna, Starlix, Tekturna (including Tekturna HCT), Diovan (including Diovan HCT) and Exforge (including Exforge HCT), when they otherwise would not have done so. Many of those prescriptions were paid for by Government funded health insurance programs.

C. FDCA and FDA Regulations

42. The FDA regulates drugs based on the "intended uses" for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a).

43. The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drug's intended uses are safe and effective. 21 U.S.C. § 355. Once a drug is approved for a particular use, doctors are free to prescribe the drug of "non-indicated" or off-label purposes. While doctors may independently request information from drug manufacturers about such off-label uses, with very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting drugs for uses, *i.e.* "indications," not approved by the FDA. As alleged above, "off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA review and approval, *i.e.*, for purposes not approved by the FDA.

44. While purely scientific or educational programs are permissible, sales and marketing presentations, promotions, or marketing to physicians for uses other than those approved by the FDA are considered off-label marketing or "misbranding" proscribed by the FDA. 21 U.S.C. §§ 331(a) – (b), 352(a), (f). Additional proscribed marketing activity includes

any attempts by a pharmaceutical sales representative to solicit discussions with physicians concerning off-label use.

45. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process and removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

46. Pursuant to the FDCA, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs.

47. The FDA interprets "labeling" in its regulations broadly to include items that are "1) descriptive of a drug; 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel." 21 C.F.R. § 202.1. The FDCA defines both misleading statements and the failure to reveal material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n). Labeling includes, among other things, brochures, booklets, detailing pieces, literature, reprints, sound recordings, exhibits and audio visual material. 21 C.F.R. § 202.1(1)(2).

48. FDA regulations deem "advertising" to include advertisements in published journals, magazines, newspapers and other periodicals, and broadcast through media such as television, radio, and telephone communications systems. *See* 21 C.F.R. § 202.1(I)(1). Courts have consistently held that oral statements made by a company's sales representative relating to a pharmaceutical product constitute commercial advertising or promotion. *See Abbott Labs. v. Mead Johnson &Co.*, 971 F.2d 6, 7 (7th Cir. 1992) (interpreting Lanham Act).

49. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance, or that are otherwise false or misleading, "misbrand" a drug in violation of the FDCA. 21 U.S.C. §§301, 321, 331, 352, 360b, 371; C.F.R. § 202.1(e)(6), (e)(7); 21 C.F.R. § 1.21.

50. Such violations exist where promotional marketing materials and presentations (*i.e.*, advertisements) for an FDA-approved drug, among other things:

- Minimize, understate, or misrepresent the side effects, contraindications and/or effectiveness of the drug;
- Overstate or misrepresent the side effects, contraindications, and/or effectiveness of competing drugs;
- Expressly or implicitly promote uses, dosages or combination usage of the drug that are not contained in the FDA-approved labeling (*i.e.*, off-label uses);
- Fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement;
- Contain representations or suggestions, not approved or permitted in the labeling, that the drug is better, more effective, useful in a broader range of conditions or patients, safer, or has fewer, or less incidence of, or less serious, side effects or contraindications than demonstrated by substantial evidence or substantial clinical experience;
- Present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does;
- Uses a quote or paraphrase out of context to convey a false or misleading idea; and/or
- Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketing or any competing drug.

21 C.F.R. § 202.1(e)(4)(5)(6), and (7).

51. Oral statements and written materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's intended use. If these statements or materials promote a use inconsistent with the product's FDA-approved labeling, the drug is misbranded, as the statements and materials fail to provide adequate directions for all intended uses.

IV. THE DRUGS

52. Lotrel, Valturna, Starlix, Tekturna (including Tekturna HCT), Diovan (including Diovan HCT) and Exforge (including Exforge HCT) are all part of NOVARTIS' CV Division.

53. Lotrel® was FDA-approved in 1995. Lotrel is indicated for the treatment of hypertension in patients not adequately controlled by monotherapy with either Amlodipine or benazepril.

54. Valturna was FDA-approved in September 2009. Valturna is indicated for the treatment of hypertension. NOVARTIS launched its Valturna marketing campaign in or about June 2010, and projects the sales of Valturna to exceed $1 billion by 2012.

55. Starlix was FDA-approved in October 2003 and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus. In 2009, Starlix generated sales of over $124 million.

56. Tekturna was FDA-approved in March 2007 and is indicated for the treatment of hypertension in adults.

57. Tekturna HCT was FDA-approved in April 2009 and is a combination of aliskiren, a direct renin inhibitor, and hydrochlorothiazide (HCTZ), a thiazide diuretic, indicated for the treatment of hypertension in patients not adequately controlled with monotherapy.

58. Diovan was FDA-approved in January 1997 and is indicated for the treatment of hypertension, both alone and in combination with other antihypertensive agents.

59. Diovan HCT was FDA-approved in March 1998 and is the combination tablet of valsartan (Diovan), an angiotensin II receptor blocker (ARB) and hydrochlorothiazide (HCTZ), a diuretic. Diovan HCT is indicated for the treatment of hypertension, to lower blood pressure in patients not adequately controlled with monotherapy.

60. Exforge was FDA-approved in June 2007 and is indicated for the treatment of hypertension in patients not adequately controlled on monotherapy.

61. Exforge HCT was FDA-approved in April 2009 and is a combination tablet of amlodipine, a dihydropyridine calcium channel blocker (DHP CCB), valsartan, an angiotensin II receptor blocker (ARB), and hydrochlorothiazide, a thiazide diuretic. Exforge HCT is indicated for the treatment of hypertension to lower blood pressure. However, Exforge HCT is not indicated as an initial therapy.

V. SUBSTANTIVE ALLEGATIONS: KICKBACKS FUELED THE CV DIVISION DRUGS

Lotrel and Starlix

62. Since its launch in 1999, Lotrel became one of NOVARTIS' top-selling anti-hypertensive drugs with annual sales reaching almost $1.3 billion in 2006.

63. Lotrel's widespread use was not a coincidence – it was the direct result of a pervasive illegal kickback carried out by NOVARTIS at the highest levels of the Company.

64. NOVARTIS utilized a multi-pronged approach to building Lotrel market share which included paying physicians cash or cash equivalents to prescribe the drug.

65. Lotrel became a big seller for NOVARTIS because it paid physicians to write Lotrel prescriptions. A program called the Novartis Consultant Network ("NCN") was instituted, as well as a wide array of other programs, as mechanisms to pay physicians to prescribe Lotrel.

66. For example, in its Long Island (NY) district, NOVARTIS implemented various schemes to facilitate its massive "pay to play" scheme including, but not limited to, arming sales representatives with Patient/Medicaid tracking cards. These cards contained 10 blank patient names. NOVARTIS sales representatives, including Plaintiff-Relator, directed physicians to fill in the cards with 10 patient names and then rewarded each compliant doctor with a payment of $100, typically in the form of cash or a gift check. These patient tracking cards were distributed by NOVARTIS District Managers to each Lotrel sales representative.

67. NOVARTIS also utilized Clinical Learning Days ("CLC"), which were a pretext to pay physicians to prescribe Lotrel and Starlix. These payments were made in the form of "honoraria" to hundreds of physicians at a time for attending lectures typically held at restaurants or hotels. NOVARTIS directed its sales representatives to aggressively recruit physicians to commit to attending these meetings with the promise of payments of $250 to $500 in return. In many cases, physicians received these payments even when the meetings were short (*i.e.*, 30-45 minutes) or even when they did not attend. So long as a physician was writing Lotrel prescriptions, he or she could expect to be paid.

68. For example, on January 23, 2008, Plaintiff-Relator, at the direction of NOVARTIS' District Manager Ishtiak Zaman ("Zaman"), arranged for a holiday party for NOVARTIS sales representatives and certain prescribers that was paid for with fraudulent

invoices under the guise of a "speakers" program. When Plaintiff-Relator balked, Zaman stated refusal to carry out his orders would be considered a "career limiting move." This exchange was witnessed by another NOVARTIS representative, Jennifer Confort. Therefore, the party went on as planned at a restaurant called FOUR in Huntington, N.Y., at a cost of $1250.00. In attendance were NOVARTIS representatives Jennifer Confort, Laurie Schuh, Sherry Battaglia, Debbie Conk, Maura Kidd, Timothy Murtha, Jeffrey Forgolu, Plaintiff-Relator and Zaman. A Lotrel prescriber, Dr. Robert Nissan, was "chosen" to receive an honorarium for this fictitious program. No doctors were actually in attendance. After being ordered to facilitate this fraudulent activity, Plaintiff-Relator reported it to another NOVARTIS District Manager, Robert Dobler, who ignored the complaint.

69. Plaintiff-Relator and other NOVARTIS sales representatives and managers conducted countless other "pay to play" events in the same manner in order to building market share for both Lotrel and Starlix.

70. NOVARTIS also encouraged the use of "preceptorships" to target and reward high volume doctors. Proper use of "preceptorships" include compensating a doctor for permitting a sales representative to accompany her in the office for an entire day. However, NOVARTIS manipulated this mechanism such that the Company routinely paid Lotrel prescribers $250 even though sales representatives spent little time with them in the office.

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73. NCN provided physicians with in-kind inducements to prescribe Lotrel, such as carts with LCD screens and sample bin organization systems. Lotrel had no true superiority

claim over the commonly prescribed Norvasc with an addition of ramapril, lisinopril or other ACEI, so the idea was to train sales representatives as speakers and for them to be present in the physicians' office buildings in conjunction with these massive bin systems and other in-kind inducements to sell more product.

74. Until in or around 2004, Defendant's sales force was allowed and encouraged to provide bogus "grants" for "symposiums" to physician practices. Notably, these grants were paid for out of the Lotrel marketing budget.

75. Physician "Roundtables" and speaker programs were also common, with the amount of the payments made to the physicians wholly subject to the discretion of NOVARTIS' sales representatives. Sometimes the audience for a speaker program was limited to a single physician in attendance. The payment provision of the contract between the NOVARTIS salesperson and the physician speaker was, up to a point, discretionary in amount. Even so, the Defendant's system enabled its sales representatives to include double and triple payments to the speaker physicians. Most speakers were trained based on their prescription potential rather than their true credentials.

76. By 2006, NOVARTIS had amassed thousands of paid Lotrel speakers and prescribers to promote wide-spread use of the drug. The effort paid off. By that time, Lotrel sales reached almost $1.3 billion.

77. Through 2004, Defendant was facilitating sales representatives to do consultancy programs, where the speaker *and attendees* were paid an honorarium for attending the program and filling out a short feedback form. Physicians were consistently reminded of their

prescription data, as representatives would personally deliver the check for payment from the consultant program.

78. In some cases, NOVARTIS sales representatives would pay physicians who prescribed Lotrel even when they did not attend a speaking engagement. These payments were sometimes made in cash that was generated by falsified receipts from third party vendors such as catering businesses.

79. Physicians who did not prescribe Lotrel would not be used and would not get paid. Generally, the speaker programs were set up by the field. Physicians who were writing the product would get programs set up for them and often times were not qualified at all. Those who did not use as much product would not be used even though they had the same (or greater) training and qualifications to speak.

80. Physician Integrated Learning Programs ("PILS") were instituted in 2006. PILS involved a physician speaker as a moderator, paid approximately $1,000 -$1,500 each time, whose job was to basically read through a book (prepared by Defendant) with the audience. At the same program, the sales force was able to select (and pay a $300 honorarium to) any other physician, to read through a sheet of scripts prepared by marketing which consisted of details about 2-3 patient types. This arrangement would allow representatives to have one physician as speaker, and pay a second physician to attend and to be the "Patient Type" presenter. The CV Division used this arrangement frequently for Lotrel, and it was also utilized in the promotional activities involving Valturna, Starlix, Tekturna, Tekturna HCT, Diovan, Diovan HCT, Exforge and Exforge HCT as well. Expenses for all of these promotional inducements were tracked according to instructions by NOVARTIS management. Budgets were allocated by drugs

(although the Lotrel budget was the major funding source), and the inducements were broken down into categories, including: "CRM funds," "access type activities," "Travel and Entertainment" funds or "Regional Educational Funds," such as a "speaker program," "Roundtable," "Lunch and Learn" or "exhibit/booth space fee."

81. NOVARTIS' paid "speakers" and/or "consultants" and "preceptorship" recipients in Plaintiff-Relator's region included, but are not limited to:

- Melissa Stockman, CS-ANP, PNP, Miller Place, NY
- Dr. Richard Cappello, Mattituck, NY
- Anna Lerner Angeles, M.D., Smithtown, NY
- Andrew Ribaudo, P.A., Selden, NY
- Robert Nissan, M.D., Huntington, NY
- Dr. Michael Weisman
- Charles Bleecher, M.D.
- Dr. John Gil
- Dr. Alan Lampert
- Janet C. Tufaro, M.D.
- Dr. Karen L. Olivieri
- Dr. Robert Mormando
- Lisa A. Carter, NP
- Dr. Edward Condon, Commack, NY
- Dr. Michael Matilsky, East Setauket, NY
- Michael Shanik, Smithtown, NY

- Ken Fishberger, Port Jefferson NY
- Mark Jagust, M.D., Lake Grove, NY
- Howard Hertz, M.D.
- Vincent Leddy, M.D.
- Ani Bodoutchian, M.D.
- Joseph Adiyody, M.D.
- Marie-Edo Desvarieux, M.D., and
- Dr. Howard Brand, Stony Brook, NY.

82. The receipt of kickbacks by many of these physicians, including Drs. Jagust, Nissan, and Condon, was particularly egregious as they each received tens of thousands of dollars in payments from NOVARTIS for prescribing CV drugs including Lotrel.

83. NOVARTIS' widespread "pay to play" scheme did not stop at cash payments. For example, during the time period at issue in this case, NOVARTIS hired Dr. Kenneth Fishberger's son, Ross, as a sales representative in the Bronx, N.Y., in order to assure that Dr. Fishberger continued to prescribe NOVARTIS' CV drugs, including Lotrel, at high levels. Likewise, NOVARTIS employed Dr. Edward Condon's daughter-in-law, Sherry Battaglia, as a sales representative in the CV division. Ms. Battaglia routinely facilitated payments to Dr. Condon for many "speaker" programs despite the blatant conflict of interest. NOVARTIS also hired Dr. Edward Condon's wife, Marybeth Condon, as a sales representative.

84. In order to assure a return of investment, NOVARTIS gave its sales representatives wide discretion on honorarium fees paid to NCN doctors in order to assure that high Lotrel and Starlix prescribers were rewarded at higher levels.

Valturna

85. After its approval by the FDA, Defendant began to promote Valturna in June, 2010.

86. A major recruitment process for additional physician speaker consultants has been ongoing by utilizing data identifying high volume prescribers.

87. Plaintiff-Relator and his colleagues were required to recruit and "develop" high volume speakers into high prescribing physicians. In order to implement this, NOVARTIS created a "Disease State Awareness Program," and in doing so contracted with physicians to talk about hypertension in general to other physicians. Valturna marketing was to focus on diabetic hypertensive patients.

88. Defendant prepared a target list to identify possible speakers. The initial list was generated by NOVARTIS' marketing department. Subsequently, the field sales force was given the opportunity to add to the list. The notion was that the physicians needed to be trained in order to get their business, so the sales force pushed for their target physicians to be trained.

89. NOVARTIS issued speaker training participant agreements and registration forms to targeted physicians. They would be registered and trained, with a physician profile filled out for each.

90. These meetings were held in large cities such as New York and Chicago. The physicians would fly in for an evening reception, followed by a one-half day training the next morning. The physicians were paid an honorarium and returned home. Alternatively, the physicians attended a teleconference in order to be "trained." While some of the tactics changed

by 2008, the goal remains the same – to pay Physician speakers for prescribing NOVARTIS drugs.

Valturna, Starlix, Tekturna, Tekturna HCT, Diovan, Diovan HCT, Exforge and Exforge HCT

91. As with the other Covered Drugs, NOVARTIS engaged in various improper and illegal means to attempt to increase the number of prescriptions being written for Valturna, Starlix, Tekturna, Tekturna HCT, Diovan, Diovan HCT, Exforge and Exforge HCT.

92. Plaintiff-Relator was present for (and in many instances was responsible – at Novartis' direction – orchestrating) multiple "office days" where physicians would be paid to purportedly speak to other physicians about Valturna, Starlix, Tekturna, Tekturna HCT, Diovan, Diovan HCT, Exforge and Exforge HCT. Although payments were made to the physicians, they never actually spoke about the drugs or otherwise provided information about the drugs to others that were present. These "office days" occurred both prior to and after the 2010 Settlement.

93. In addition to witnessing first-hand the payments for speeches that were never delivered by physicians (which payments were made with the sole purpose of increasing the number of prescriptions written), Plaintiff-Relator was also made aware of the improper methods being used through conversations with sales representatives on his team. Through conversations with, among others, Sherry Bataglia and Laurie Schuh, Plaintiff-Relator knew that NOVARTIS was engaging in the same type of conduct in pushing prescriptions for Tekturna, Diovan and Exforge as is described above relative to the drugs Lotrel, Valturna and Starlix.

94. The information provided by Sherry Bataglia, Laurie Schuh and others confirmed that the improper conduct being directed by NOVARTIS occurred both before and after the 2010 Settlement.

A. No Legitimate Need for the Services, or Use of the Services

95. Physician attendance at speaker events was sparse. It was not uncommon for there to be only one or two physicians present. In some cases, no physicians attended, yet they were still paid.

96. Defendant eventually implemented software which required the sales force to enter the names of a minimum of three healthcare providers who attended the program; it was a mandatory-minimum, or the speaker would not get paid. Salespersons would write down doctors' names even if they did not attend; they used the names of physicians who were either frequent prescribers or friends. There was no oversight by Defendant to ensure the accuracy of the reporting. Indeed, NOVARTIS management was at many of the programs where less than three healthcare providers in total were present.

97. Speakers were continually used and paid, even though some could not communicate at an acceptable level. Several speakers had difficulty with English. Other speakers were simply very poor communicators. Most physicians were selected based upon criteria related to prescription writing, and not to the purpose of the services identified in the contract. They often did not have the expertise level necessary for a physician to be a "consultant," in the specific sub-fields of cardiology that they were paid to speak about.

B. The Number of Consultants Retained Far Exceeded the Number of Consultants Reasonably Necessary to Achieve the Purpose of the Consultants

98. By the time Valturna was rolled out, there were thousands of "speakers" and "consultants" on NOVARTIS' CV payroll. Nearly every doctor was a speaker – any doctor who wanted could be a speaker. As NOVARTIS' latest hypertensive drug, Valturna, was set to

launch in September, 2009, NOVARTIS directed its sales representatives to utilize its "pay to play" network to promote Valturna as the Company knew that very few physicians would (without inducements) write prescriptions for Valturna because the drugs offered nothing better than existing drugs, even generics.

99. The number of "speakers" and "consultants" were excessive. For instance, in New York, there were hundreds, if not more.

C. "Consultants" Compensation Was in Excess of "Fair Market Value" Through at least 2007

100. Speaker consultant honorarium amounts were set at the sales force discretion, within a range. The sales force was were never questioned as to how much they were paying consultants. Honorariums were paid to attendees through 2004.

101. At the end of 2007, NOVARTIS announced the results of a fair market value speaker honoraria report. The report allegedly concluded that $1,500 and even $2,000 was fair market value to pay speakers. NOVARTIS told Plaintiff-Relator and his colleagues to pay only these amounts, and directed them that if the physician were to get upset over those amounts (*i.e.*, too low), they should use the internal appeals process.

D. NOVARTIS conducted return on investment analysis

102. Once a physician was in the Company's speaker system, it was up to Plaintiff-Relator and his colleagues to ensure that the physician was "on message," meaning that he had plenty of "experience" with the product, a favorable outlook on the product, and had the ability to stand up and speak and convince other physicians to prescribe the product. NOVARTIS speakers were often paid to speak repeatedly to the same offices or even to other physicians within their own practice. Regional Directors required speakers to be prescribing products in

adequate numbers. If they were not, Plaintiff-Relator and colleagues were required to tell physicians that they would no longer be allowed to be speakers unless they increased their prescriptions to a certain level. Defendant issued reprimands to the sales force when physicians were paid as consultants yet were not meeting minimum prescription levels.

103. While pharmaceutical companies need insight from physicians to improve drug treatments, the communications should be based upon legitimate need, and the consultants should be "bona fide." The consultant payments alleged herein, however, were based on the volume of prescriptions that physicians could continue to, or potentially write.

VI. OTHER VIOLATIONS

Off-label

104. NOVARTIS' blockbuster hypertension drug, Diovan, generated sales of over $4 billion in 2009. NOVARTIS' patent on Diovan is set to expire in 2012.

105. NOVARTIS' strategy for making up for lost Diovan dollars post-patent expiration includes building market share of Valturna. The company at regional & local district planning meetings informed representatives that speakers in particular were to begin transitioning Diovan patients to Valturna or they would lose priority in further training. Speakers that were not "on board" with Valturna were cut in October of 2010 for future engagements in 2011. NOVARTIS told its sales representatives, including Plaintiff-Relator, **not** to communicate this status to the speakers to assure that they would "stay on board" until the very end.

106. NOVARTIS' strategy for building Valturna's market share to make up for the anticipated lost Diovan sales involved marketing to diabetic patients who may experience high blood pressure, not hypertensive patients who are adequately controlled on existing therapies.

- This off-label promotion is even more egregious considering NOVARTIS' 2010 settlement with the Department of Justice which includes settlement of claims that NOVARTIS misbranded and/or otherwise marketed Diovan for unapproved uses, including to diabetics. The Diovan off-label claims at issue in that case were bolstered by the fact that on April 21, 2004, the FDA's Division of Drug Marketing issued a warning letter to NOVARTIS with regard to a sales aid that claimed that Diovan is effective in treating patients with type 2 diabetes and hypertension to preserve renal function.
- The FDA ordered Defendant to immediately cease the dissemination of all promotional materials for Diovan that contained such claims and to provide a plan to disseminate accurate and complete information. However, as detailed in the *qui tam* complaint captioned as *U.S. ex. rel. James Garrity v. Novartis Pharma. Corp.*, 08-CV-2588 (E.D. Pa.), NOVARTIS continued to market Diovan for off-label uses.

107. Despite having been warned in 2004 about promoting Diovan for treating type 2 diabetics and later entering into a settlement agreement with the Government that was based, in part, on this misbranding and/or off-label promotion of Diovan, NOVARTIS is at it again.

108. Since launching its Valturna promotional campaign in June 2010, NOVARTIS has expressly directed its sales force to piggyback its kickback scheme with unapproved, off-label information including claims that Valturna is medically appropriate for the treatment of hypertension in ***diabetic patients***.

109. As it had done in the past with Diovan, in order to successfully carry out this off-label promotion, Defendant conducted national sales meetings, regional and district meetings, designed specifically for the purpose of training representatives on off-label sales and marketing practices.

110. In addition, NOVARTIS armed its sales representatives with numerous detailed promotional pieces that it distributed directly to primary care physicians, internists, and endocrinologists, among others.

111. For example, on or about September 9, 2010 (around the same time that NOVARTIS' settlement with the Government was being announced in the *Garrity qui tam* action), NOVARTIS Managing Director Richard Scatoni and NOVARTIS District Manager Robert Dobler conducted a regional planning meeting at the Islandia Marriott hotel in Islandia, N.Y. At this meeting, Mr. Scatoni and Mr. Dobler stated emphatically that Valturna was the ONLY hypertensive drug to work in the kidney when in fact numerous other drugs do so, including several generic diuretics. Plaintiff-Relator was given a placard to be used in the field that illustrates that hypertensive diabetics in particular would benefit from utilizing Valturna, even though the drug was not indicated for that purpose in particular. Incredibly, this is the same type of misconduct for which NOVARTIS was admonished by the FDA with regard to Diovan and which led, in part, to the prior *qui tam* settlement.

112. In addition, while the Valturna placard improperly emphasized use of the drug in diabetics, the piece included illustrations of rodent data that the Company consistently told representatives to avoid discussing. In other words, doctors were led to believe that the data being discussed involved humans.

113. Other uniform and widespread tactics used by Defendant to promote off-label, in conjunction with kickbacks, also included hiding behind "CME" Speaker Programs via physicians and other healthcare providers to promote off-label usage. These programs were controlled and promoted by Defendant.

114. As a result of these tactics, when healthcare providers expressly certified, as a precondition to payment, that they would comply with the terms set out on Form HCFA-1500 (which includes language that the services were "medically indicated and necessary for the health of the patient") and other claims for payment, the claims they submitted were false because the drugs were neither medically indicated and necessary, for the off-label uses, under Government Healthcare Programs, as explained below.

A. Claims Submitted to Government Healthcare Programs for Off-Label Uses Were Not Covered

115. In the Medicaid Program, States will not receive FFP ("Federal Financial Participation") if a drug, as prescribed, is not for a medically acceptable use. FFP is available to States only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). As a result, States' own laws and pharmacy regulations require that drugs must be used for a medically accepted use and therefore fit the definition of a covered outpatient drug. "Covered outpatient drugs" do not include drugs that are "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A medically accepted indication is defined as a use "which is approved under the [FDCA]" or which is "supported by one or more citations included or approved for inclusion" in specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). 42 U.S.C.§ 1396r-8(g)(1)(B)(I) identifies the compendia to be consulted: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX

Information System. The compendia will hereinafter be referred to collectively as "the Drug Compendia."

Medicare

116. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e – 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting, and are "reasonable and necessary."

117. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting, and that are "reasonable and necessary." 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517. These typically include drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics (drugs which control the side effects caused by chemotherapy), and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517.

118. The Medicare program Part D drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k).

119. The off-label uses alleged herein are not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted as safe and effective" or "reasonable and necessary" for such uses. Claims for such off-label uses were therefore not covered by Medicare either.

120. Defendant was aware that the natural and probable consequence of its promotion of off-label uses of Valturna was that health care providers would submit claims for payment to Government Healthcare Programs for the off-label use.

121. Notwithstanding this knowledge, Defendant illegally, vigorously, and without any thought to the possible negative health effects to which it subjected patients, promoted these off-label uses. Defendant was aware that its illegal promotion did in fact result in false claims to these and other government payors for the off-label uses. Defendant was aware that its promotion activities was a substantial factor in producing the claims.

122. When pharmacies, physicians and other healthcare providers submitted claims based upon a physician's prescription for Valturnafor off-label uses, the claims they submitted were false because such off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(I) (Medicaid), not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective"or "reasonable and necessary" (Medicare), and not covered by other Government Healthcare Programs. *See, e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

123. False claims to these government healthcare programs for off-label prescribing was the direct and proximate result of unlawful off-label marketing efforts by Defendant. Defendant caused the submission of these claims.

124. Defendant caused the submission of false claims, since healthcare providers submitted Pharmacy Claim Forms and CMS-1500 Forms to Government Healthcare Programs, and the States submitted Form CMS-64 to the Federal Government, all claiming reimbursement for Valturna, for such off-label uses.

VII. CONCLUSION

125. The decision-making of the physician, that important element in Government Program coverage policy, was completely undermined by the unlawful marketing of Defendant. The physicians prescribing Defendant's drugs did not necessarily do so because they believed, based on their review of peer-reviewed medical literature, or discussions with their colleagues, that the drugs would help their patients; rather the drugs were often prescribed because the physicians were actively pursued and enticed by NOVARTIS with kickbacks.

COUNT I – FCA

126. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

127. This is a claim by Plaintiff-Relator, on behalf of The United States, for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3733, against Defendant for knowingly causing to be presented false claims to Government Healthcare Programs. From on or about January 2002 through present, in the Southern District of New York and elsewhere throughout the United States, Defendant has knowingly and willfully violated the False Claims Act by submitting and causing false claims to be submitted.

128. Defendant has knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment, knowing that such false claims would be submitted to state Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for prescriptions induced by kickbacks and/or for non-covered uses and therefore false claims. By virtue of the acts alleged herein, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2).

129. For all unlawful conduct for which Defendant is liable under this Count that occurred on or after May 20, 2009, the date on which Congress amended and renumbered the Federal False Claims Act pursuant to the Fraud Enforcement and Recovery Act ("FERA"), Pub.L.No. 111-21, §4, 123 Stat. 1617, 1621 (2009), this First Amended Complaint should be

deemed to include violations of the FCA after the FERA amendments, specifically, 31 U.S.C. §3729(a)(1)(A) and 31 U.S.C. §3729(a)(1)(B).

130. Defendant has violated 31 U.S.C. § 3729(a)(2) by causing the States to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Valturna, were paid for in compliance with federal law. States submitted false claims to the United States Government because when Valturna, wasprescribed off-label, it was not prescribed for a medically accepted indication, yet States sought reimbursement from the United States Government for all Valturna expenditures.

131. Defendant caused false claims to be submitted, resulting in Government Program reimbursement to healthcare providers in the millions of dollars, in violation of the False Claims Act, 31 U.S.C. § 3729 et. seq. and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b)(2)(A).

132. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

WHEREFORE, Plaintiff-Relator respectfully requests this Court enter judgment against Defendant, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.* provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendant caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT II – ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

133. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

134. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq*.

135. 740 ILCS 175/3(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

136. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

137. Defendant violated 305 ILCS 5/8A-3(b) by engaging in the conduct alleged herein.

138. Defendant furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

139. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

140. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendant's conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

141. Had the State of Illinois known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

142. As a result of Defendant's violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

143. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

144. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF ILLINOIS:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT III – CALIFORNIA FALSE CLAIMS ACT

145. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

146. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

147. Cal. Gov't Code § 12651(a) provides liability for any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
>
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
>
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

148. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

149. Defendant violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the conduct alleged herein.

150. Defendant furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

151. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

152. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of California in connection with Defendant's conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

153. Had the State of California known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

154. As a result of Defendant's violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

155. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

156. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendant's conduct;

(2) A civil penalty of up to $10,000 for each false claim which Defendant presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT IV – FLORIDA FALSE CLAIMS ACT

157. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

158. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

159. Fla. Stat. § 68.082(2) provides liability for any person who-

> (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;
>
> (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed-or paid.

160. In addition, Fla. Stat. § 409.920 makes it a crime to:

> (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;
>
> * * *
>
> (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

161. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

162. Defendant violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct alleged herein.

163. Defendant further violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

164. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

165. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendant's conduct. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.

166. Had the State of Florida known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were

premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

167. As a result of Defendant's violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

168. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

169. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully request this Court to award the following damages to the following parties and against Defendant:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT V – TEXAS FALSE CLAIMS ACT

170. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

171. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

172. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who-

> (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
>
> (a) on an application for a contract, benefit, or payment under the Medicaid program; or
>
> (b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.
>
> (2) knowingly or intentionally concealing or failing to disclose an event:
>
> (a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:
>
> (i) the person, or
>
> (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
>
> (b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
>
> * * *
>
> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

> * * *
> (b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
>
> (5) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

173. Defendant violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-kickback Act and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

174. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

175. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendant's conduct. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

176. Had the State of Texas known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed

to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

177. As a result of Defendant's violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

178. Defendant did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and has not otherwise furnished information to the State regarding the claims for reimbursement at issue.

179. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

180. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF TEXAS:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $10,000 pursuant to V.T.C.A. Hum.. Res. Code § 36.025(a)(3) for each false claim which Defendant cause to be presented to the state of Texas;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VI – MASSACHUSETTS FALSE CLAIMS ACT

181. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

182. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) *et seq.*

183. Mass. Gen. Laws Ann. Chap. 12 § 5B provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

* * *

> (9) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

184. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

185. Defendant violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the conduct alleged herein.

186. Defendant further violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Ann. Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

187. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

188. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express

condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendant's conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

189. Had the Commonwealth of Massachusetts known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

190. As a result of Defendant's violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

191. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

192. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the Commonwealth OF MASSACHUSETTS:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Massachusetts;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, §5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VII – TENNESSEE FALSE CLAIMS ACT

193. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

194. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

195. Section 71-5-182(a)(1) provides liability for any person who-

(A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

196. Defendant violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

197. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

198. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendant's conduct. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.

199. Had the State of Tennessee known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

200. As a result of Defendant's violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

201. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

202. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF TENNESSEE:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Tennessee;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VIII – DELAWARE FALSE CLAIMS AND REPORTING ACT

203. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

204. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

205. 6 Del. C. § 1201(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

206. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

207. Defendant violated 31 Del. C. § 1005 by engaging in the conduct alleged herein.

208. Defendant further violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws, including the FDCA, the Anti-

Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

209. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

210. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendant's conduct. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.

211. Had the State of Delaware known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

212. As a result of Defendant's violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

213. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

214. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF DELAWARE:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Delaware;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT IX – NEVADA FALSE CLAIMS ACT

215. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

216. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et. seq.*

217. N.R.S. § 357.040(1) provides liability for any person who -

> (a) knowingly presents or causes to be presented a false claim for payment or approval;
> (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
> (c) conspires to defraud by obtaining allowance or payment of a false claim;
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

218. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

219. Defendant violated N.R.S. § 422.560 by engaging in the conduct alleged herein.

220. Defendant further violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and N.R.S. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

221. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendant' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

222. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendant's conduct. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.

223. Had the State of Nevada known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

224. As a result of Defendant's violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

225. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

226. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests that this Court award the following damages to the following parties and against Defendant:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Nevada;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT X – LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

227. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

228. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

229. La. Rev. Stat. Ann. § 438.3 provides-

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;

> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

230. In addition, La. Rev. Stat. Ann. § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes and/or rebates, directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for in whole or in part by the Louisiana medical assistance programs.

231. Defendant violated La. Rev. Stat. Ann. § 438.2(A) by engaging in the conduct alleged herein.

232. Defendant further violated La. Rev. Stat. Ann. §438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and La. Rev. Stat. Ann. § 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

233. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendant's' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

234. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendant's conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

235. Had the State of Louisiana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

236. As a result of Defendant's violations of La. Rev. Stat. Ann. § 438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

237. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of himself and the State of Louisiana.

238. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Louisiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XI – HAWAII FALSE CLAIMS ACT

239. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

240. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

241. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or d by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
>
> * * *
>
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

242. Defendant violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds

of thousands of false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FDCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

243. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

244. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendant's conduct. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.

245. Had the State of Hawaii known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

246. As a result of Defendant's violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

247. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

248. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the STATE OF HAWAII:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendant's illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Hawaii;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XII – D.C. PROCUREMENT REFORM AMENDMENT ACT

249. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

250. This is a *qui tam* action brought by Plaintiff-Relator and the District of Columbia

to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

251. D.C. Code § 2-308.14(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District, a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
>
> * * *
>
> (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

252. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program, or
> (2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

253. Defendant violated D.C. Code § 4-802(c) by engaging in the illegal conduct alleged herein.

254. Defendant further violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-

funded healthcare programs.

255. The District of Columbia, by and through the District of Columbia Medicaid program and other District healthcare programs, and unaware of Defendant's illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

256. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Defendant's illegal conduct. Compliance with applicable D.C. statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District of Columbia.

257. Had the District of Columbia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

258. As a result of Defendant's violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

259. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

260. This Court is requested to accept supplemental jurisdiction of this related state

claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the DISTRICT OF COLUMBIA:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendant's illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the District of Columbia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIII – VIRGINIA FRAUD AGAINST TAX PAYERS ACT

261. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

262. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Tax

Payers Act, §8.01-216.3a, which provides liability for any person who-

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
>
> * * *
>
> (9) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

263. In addition, VA Code Ann. § 32.1-315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Virginia Medicaid program.

264. Defendant violated VA Code Ann. § 32.1-315 by engaging in the conduct alleged herein.

265. Defendant furthermore violated Virginia's Fraud Against Tax Payers Act, § 8.01-216.3a, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, VA Code Ann. § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

266. The Commonwealth of Virginia, by and through the Virginia Medicaid program

and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

267. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendant's conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

268. Had the Commonwealth of Virginia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

269. As a result of Defendant's violations of Virginia's Fraud Against Tax Payers Act, §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

270. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Virginia's Fraud Against Tax Payers Act, §8.01-216.3, on behalf of himself and the Commonwealth of Virginia.

271. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts

separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

To the COMMONWEALTH OF VIRGINIA:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Virginia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Plaintiff-Relator:

(1) The maximum amount allowed pursuant to VA Code Ann. § 32.1-315 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XIV – THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS LAW

272. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

273. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims Law, N.H. Rev. Stat. Ann. § 167:61-b, which provides that: